

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paper Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/800,898	
	Filing Date	3/15/2004	
	First Named Inventor	Jules A. Shafer	
	Art Unit	1614	
	Examiner Name		
Total Number of Pages in This Submission	91	Attorney Docket Number	03-03US

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance communication to (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO Form 1449 (2 pages) International Search Report (2 pages) Return Receipt Postcard Copies of References as listed on form 1449 (84 pages)
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

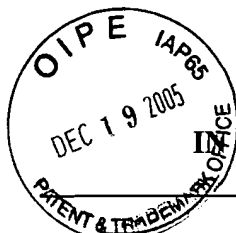
Firm Name	Nastech Pharmaceutical Company Inc.		
Signature			
Printed name	Peter J. Knudsen		
Date	December 15, 2005	Reg. No.	40682

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature			
Typed or printed name	Jeffrey L. Granger	Date	December 15, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

In you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Shafer et al.

Serial No.: 10/800,898

Filed: 3/15/2004

Title: COMPOUNDS AND METHODS
FOR LOWERING THE ABUSE
POTENTIAL AND EXTENDING
THE DURATION OF ACTION OF A
DRUG

Attorney Docket No.: 03-03US

Assignee: Controlled Chemicals, Inc.
(Reel/Frame: 014714/0264)

Group Art Unit: 1614

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Information Disclosure Statement is submitted:

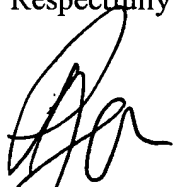
- ☒ under 37 CFR 1.97(b), or
(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- ☐ under 37 CFR 1.97(c) together with either a:
☐ Statement under 37 CFR 1.97(e), or
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with a:
☐ Statement under 37 CFR 1.97(e), and
☐ a \$180.00 fee set forth in 37 CFR 1.17(p).
(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

☒ Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

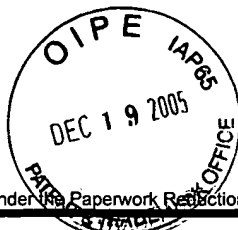
The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,



Peter J. Knudsen
Attorney/Agent for Applicant(s)
Reg. No. 40682
Date: December 15, 2005
Nastech Pharmaceutical Company Inc.
3450 Monte Villa Parkway
Bothell, WA 98021-8906
Telephone No.: 425-908-3643
pknudsen@nastech.com



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO/SB/08a (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/800,898
Filing Date	3/15/2004
First Named Inventor	Shafer et al.
Art Unit	1614
Examiner Name	
Attorney Docket Number	03-03US

Sheet 1 of 2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-3,299,072	Issued 01-17-1967	Smith Kline & French Laboratories	
		US-3,966,940	Issued 06-29-1976	Bristol-Myers Company	
		US-4,457,933	Issued 07-03-1984	Bristol-Myers Company	
		US-4,489,065	Issued 12-18-1984	Valcor Scientific, Limited	
		US-4,661,492	Issued 04-28-1987	Reckitt & Colman Products Limited	
		US-4,769,372	Issued 09-06-1988	The Rockefeller University	
		US-4,785,000	Issued 11-15-1988	The Rockefeller University	
		US-5,130,126	Issued 07-14-1992	Nippon Oil & Fats Co., Ltd.	
		US-5,149,538	Issued 09-22-1992	Warner-Lambert Company	
		US-5,176,907	Issued 01-05-1993	The Johns Hopkins University School of Medicine	
		US-5,194,581	Issued 03-16-1993	Leong	
		US-5,236,714	Issued 08-17-1993	Alza Corporation	
		US-6,051,576	Issued 04-18-2000	University of Kentucky Research Foundation	
		US-6,228,863	Issued 05-08-2001	Euro-Celtique S.A.	
		US-6,277,384	Issued 08-21-2001	Euro-Celtique S.A.	
		US-6,375,957	Issued 04-23-2002	Euro-Celtique S.A.	
		US-6,451,806	Issued 09-17-2002	Aldolor Corporation	
		US-6,475,494	Issued 11-05-2002	Euro-Celtique S.A.	
		US 2003/0022876 A1	01-30-2003	Ashton et al	
		US 2004/0058946 A1	03-25-2004	Buchwald et al	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		GB 1 300 419	12-20-1972	Organon Laboratories Limited		
		EP 1 258 246	11-20-2002	Euro-Celtique S.A.		
		WO 02/094254 A2	11-28-2002	Endo Pharmaceuticals, Inc.		

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b (07-05)

Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

2

of

2

Complete if Known

Application Number 10/800,898

Filing Date 3/15/2004

First Named Inventor Shafer et al.

Art Unit 1614

Examiner Name

Attorney Docket Number 03-03US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		AGARWAL, V. and MISHRA, B.; "Design, Development, and Biopharmaceutical Properties of Buccoadhesive Compacts of Pentazocine;" <i>Drug Dev. Ind. Pharm</i> ; June 1999; 25 (6); 701-709	
		BUCKETT, W. R.; "THE RELATIONSHIP BETWEEN ANALGESIC ACTIVITY, ACUTE TOXICITY AND CHEMICAL STRUCTURE INESTERS OF 14-HYDROXYCODEINONE;" <i>J Pharm Pharmacol</i> ; December 1964; 16 SUPPL-71T	
		BUCKETT, W. R.; FARQUHARSON, M. E.; and HAINING, C. G.; "THE ANALGESIC PROPERTIES OF SOME 14-SUBSTITUTED DERIVATIVES OF CODEINE AND CODEINONE;" <i>J Pharm Pharmacol</i> ; March 1964; 16 174-182	
		OKUDA, T.; TSUCHIYA, N.; WAKITA, K.; HATSUOKA, K.; KOGA, Y.; UEDA, S.; and KAETSU, I.; "[Prolonged Antinociceptive Effect After Epidural Injection of Polyethylene Glycol-Morphine Composites in Rats];" <i>Masui</i> ; May 1996; 45 (5); 571-575	
		NAGASE et al.; "The Facility of Formation of a Δ^8 Bond in Dihydromorphinone and Related Opiates;" <i>J. Org. Chem.</i> ; 1989, vol. 54; 4120-4125	
		HANSEN, H. C. and SPILLUM, A.; "Loss of Nitroglycerin During Passage Through Two Different Infusion Sets;" <i>Acta Pharm Nord.</i> ; 1991; 3 (3); 131-136	
		HOSZTAFI, S.; KOHEGYI, I.; SIMON, C.; and FURST, Z.; "Synthesis and Analgetic Activity of Nicotinic Esters of Morphine Derivatives;" <i>Arzneimittelforschung.</i> ; November 1993; 43 (11); 1200-1203	
		HUSSAIN, M. A.; AUNGST, B. J.; KOVAL, C. A.; and SHEFTER, E.; "Improved Buccal Delivery of Opioid Analgesics and Antagonists With Bitterless Prodrugs;" <i>Pharm Res</i> ; September 1988; 5 (9); 615-618	
		STINCHCOMB, A. L.; PALIWAL, A.; DUA, R.; IMOTO, H.; WOODARD, R. W.; and FLYNN, G. L.; "Permeation of Buprenorphine and Its 3-Alkyl-Ester Prodrugs Through Human Skin;" <i>Pharm Res</i> ; October 1996; 13 (10); 1519-1523	
		STINCHCOMB, A. L.; SWAAN, P. W.; EKABO, O.; HARRIS, K. K.; BROWE, J.; HAMMELL, D. C.; COOPERMAN, T. A.; and PEARSALL, M.; "Straight-Chain Naltrexone Ester Prodrugs: Diffusion and Concurrent Esterase Biotransformation in Human Skin;" <i>J Pharm Sci</i> ; December 2002; 91 (12); 2571-2578	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.